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DADE BEHRING INC.
LEGAL DEPARTMENT
1717 DEERFIELD ROAD
DEERFIELD, IL 60015

EXAMINER	
GAKH, YELENA G	

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1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,079	DEVLIN ET AL.	
	Examiner	Art Unit	
	Yelena G. Gakh, Ph.D.	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 June 2008 and 27 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-2 and 4-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. RCE, filed on 06/19/08 and amendment, filed on 05/27/08, are acknowledged. Claim 3 is cancelled. Claims 1-2 and 4-11 are pending in the application.

Response to Amendment

2. Objection to the amendment as introducing new matter is withdrawn in light of the Applicants' remarks.

Rejections under 35 U.S.C. 112, second paragraph, and over the prior art, are maintained.

Claim Objections

3. Claim 7 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 7 recites the step of "providing a bar coded indicia on said sample container containing information that can be used to establish the period of time that the second sample aliquot is retained in the storage compartment after tests on the first sample aliquot are completed." Claim 1 recites "providing bar code indicia on the original sample container to indicate a predetermined period of storage time." The examiner considers the subject matter of claim 7 as being included in the recitation of claim 1; therefore, claim 7 does not further limit the subject matter of claim 1.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-2 and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites “providing bar code indicia on the original sample container to indicate a predetermined period of storage time”. It is not apparent, as to how the period of storage time is

related to the test to be performed with the first aliquot of the sample, recited in the preamble of the claim. Is it the storage time related to expiration date of the sample? Is it some other predetermined storage time? Further, it is not apparent, as to where the first aliquot portion of the patient specimen is deposited after extraction. It appears, that the first portion is not deposited anywhere, while the second portion is deposited into the aliquot storage vessel. Is the first portion retained in the extraction means? Does it mean that there should a different extraction means for extracting the second aliquot portion of the sample, since the first extraction means are filled with the first aliquot portion? The steps of the method, while being quite detailed, raise an issue of indefiniteness and unclarity.

Moreover, the recitation of claim 1 is contradictory. While in the preamble claim 1 recites that additional tests are performed *after* the tests on the first aliquot are completed, in the last method step it recites that the tests on the second aliquot sample are performed *during* said period of time, i.e. when the tests on the first aliquot are not yet completed, since (to the examiner's understanding) the tests time define the storage time.

Claim 7 recites "the method of claim 1 wherein marking the sample container to indicate a period of time comprises ...". Claim 1 does not recite "marking the sample container to indicate a period of time", which means that the limitation of claim 7 does not have antecedent basis. Furthermore, it is not clear as to how the step of "providing a bar coded indicia on said sample container containing information that can be used to establish the period of time that the second sample aliquot is retained in the storage compartment after tests on the first sample aliquot are completed" recited in claim 7 is related to the step of "providing bar code indicia on the original sample container to indicate a predetermined period of storage time" recited in the parent claim.

Claim 8 is unclear in the same way, as claim 1. It is not clear, what is relation between the identity of the tests to be performed on the first aliquot and the storage tine of the second aliquot. Should the storage time be longer than the time for the performed tests? Also, it is not apparent, as to where the first aliquot portion of the patient specimen is deposited after extraction. It appears, that the first portion is not deposited anywhere, while the second portion is deposited into the aliquot storage vessel. Is the first portion retained in the extraction means? Does it mean that there should a different extraction means for extracting the second aliquot

portion of the sample, since the first extraction means are filled with the first aliquot portion? It is also not apparent, as to what is "using the identity of said tests to determine a storage period of time for said second aliquot portion". What is "identity of the tests", and how this identity can be used to define the storage period of time for the sample? Further, it is not clear, as to how the second aliquot specimen portion can be analyzed *during* the storage period of time, when the storage period of time is defined by the tests performed with the first aliquot, and the second aliquot should be tested (according to the preamble of the claim) *after* the first aliquot tests are completed? It appears that claim 8 recites contradictory subject matter.

Claim 9 is unclear. Claim 1 recites "providing bar code indicia on the original sample container to indicate a predetermined period of storage time". Claim 9 recites "wherein the bar code indicia on the original sample container indicate a period of time associated with each of the multiple analytes". It is unapparent, as to what may be the "period of time associated with each of the multiple analytes". Is it supposed to mean that there are specific tests associates with each of the multiple analytes, which define the time for performing the test? If this is what was supposed to be recited in the claim, the examiner requests the Applicants to write this in a clear and definite way. Further, claim 9 recites a contradictory subject matter in the same way, as claims 1 and 8. Claim 1 in its preamble indicates that additional tests are performed *after* the tests on the first aliquot are completed. At the same time claim 9 recites "additionally testing the second aliquot specimen portion *during* said predetermined period of time." If the time is defined by the test time of the first aliquot, how can the test with the second aliquot be performed *during* this period of time, if the test with the firs aliquot should be *completed*?

The same is true for claim 10.

Claim 11 is unclear. It is not apparent, as to what should define "whether or not the second aliquot portion is to be retained in storage", and how the period of storage time is determined.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1-2, 5, 7-9 and 11** are rejected under 35 U.S.C. 102(b) as being anticipated by Young et al. (US 3,565,582) (Young).

Young teaches "methods and means for handling blood test specimens", with the method comprising the following steps:

"some of the serum is transferred from the initial or first vessel to the other or second vessel. A sample of the specimen is withdrawn and is subjected to the test sequence which includes the testing and presentation of the test result. These steps, withdrawal of the sample, testing and presentation of test results are accomplished according to a predefined time schedule. An added step in the process, and one which may be accomplished at any point in the process this far described, is to apply to the container indicia or data which will identify the specimen and the test to which it is to be subjected" (col. 3, lines 60-72). "*Upon withdrawal of a test sample a specimen upon which other tests are to be run is placed in storage and is then submitted to another timed sequence of steps including sample withdrawal, testing and presentation of test results. The storage step may be included in the time sequence of the steps. The step of reading the data in the container and correlating that data with test results will also be included in the timed sequence of steps*" (col. 4, lines 10-16).

The method also comprises providing:

"a double vessel container for blood and its serum, which is capable of bearing data identifying the blood and the test prescribed together with apparatus for reading that data and for conducting tests according to a predetermined relative time schedule" (col. 3, lines 48-53).

"It is implicit in the preceding discussion that the several steps in the method may be separated by storage steps in which specimens are stored in the double vessel container. Any storage prior to application of identification data to the container must be controlled to prevent loss of identity. *In addition, in the interval between removal of the sample and correlation of identification data and test result there must be a control to enable proper correlation which involves accomplishment of any storage steps on a timed basis for integral multiples of the unit time period employed in the process*" (col. 8, lines 10-20) (which depends on the test to be performed, see col. 7).

"A cover 44 is provided for the container to insure cleanliness prior to use and to insure that the blood and serum are not contaminated with dirt and other foreign matter once they are placed in the container" (col. 6, lines 19-22).

Young discloses a method performed on the apparatus, which is a predecessor of convention modern automatic analyzers, well known in the prior art, and thus the container indicia with "data applicator" is analogous to conventional modern bar code indicia. The

examiner believes that the disclosure in terms, which were conventional for the state of the prior art in the time of Young's invention, covers the subject matter of the indicated claims.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. **Claims 4, 6 and 10** are rejected under 35 U.S.C. 102(b) as being unpatentable over Young et al. (US 3,565,582) (Young).

While Young does not specifically disclose an aliquot strip having a number of open aliquot wells (claim 4), and disposing the sample or displaying an alert signal after the storage time expires, using aliquot strips is conventional of automated analysis of biological samples in the art; regarding claims 6 and 10 Young teaches: "it is to be noted, and it is a feature of the invention, that the method imposes no limitation on the time during which tests must be conducted except for that the maximum time for conducting tests must be known". It would have been obvious for a person of ordinary skill in the art to set an alert system and dispose the sample which storage time exceeded the maximum time for analysis.

10. **Claims 1-2, 4, 6-11** are rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza (US 5,350,564, IDS) in view of Thorne et al. (US 4,678,752, IDS).

Mazza discloses, “the present invention relates to an adaptive, versatile conveyor system for feeding individual sample tubes, cells, *cuvettes*, and the like (hereinafter collectively referred to as "sample tubes") each held in an individual prismatic sample tube carrier, either from associated groups or batches which are taken in regular order, or from a stat sample area taken with priority; identifying the individual sample tubes; conveying and/or temporarily storing the individual sample tubes as required; transferring the individual sample tubes to and from one or more associated analysis modules of the apparatus as appropriate; ***retaining the individual sample tubes in temporary storage while test results are obtained, and returning the individual sample tubes to associated groups in response to an indication that analysis of a particular sample is complete and verified as reliable***. The present invention has particular utility for use in automated chemical analyzers and related equipment for analysis and testing of blood, physiological fluids, and other biological samples” (col. 1, lines 18-38); “the carriers are

individually fed to a rotator assembly which provides both for the *reading of a bar code tag on the sample tube* in the carrier, and the rotational orientation of the carrier in a particular presentation" (col. 5, lines 20-24). Sample carriers returned from an analyzer to the loop conveyor are retained thereon, along with incoming samples en route to an analyzer, and priority stat samples which will be received by an analyzer prior to the rank and file samples, until the results of the tests on the sample are confirmed. Thus, the loop conveyor provides a dwell capacity in association with the analyzer. This dwell capacity also allows rank and file samples to be held in abeyance on the loop conveyor while stat samples traverse the conveyor immediately en route to the analyzer. *In the event the test results are not confirmed, the particular sample may be fed from the loop conveyor back to the analyzer for a second or subsequent testing*" (col. 5, lines 33-43).

"The entire operation of the conveyor is under the control of a dynamic controller so that each discreet action with respect to a sample carrier from the time its sample is identified until the sample test results are verified and the carrier is off loaded is tracked. Thus, test results are easily correlated with a particular sample and patient. Also, the location of each sample on the loop conveyor, and of vacant receptacles, which are available for receipt of a stat or of a rank and file sample, is always recorded. *This feature of the conveyor along with its storage and dwell time feature makes possible the recall to an analyzer module of any particular sample in the event the results of a test are not verified as reliable*. This latter feature is of high importance with stat samples. If the test results for any start sample are not reliable, the sample will be recalled to the analyzer and retested. Only when the test results of each sample are verified will the sample be delivered to the off-loading area" (col. 5, lines 56-68, col. 6, lines 1-6).

Mazza does not specifically indicate that the bar code on the sample container has information on the time period for the sample to be retained at the storage compartment.

Thorne discloses an automatic random access analyzer comprising an environmentally controlled (col. 10, lines 60-67) incubation storage area 18 within the analyzer for storing a plurality of reagent packages comprising reagent solutions, with the packages having barcode labels 46 with the information on expiration date (col. 5, lines 60-68). The reagents are automatically extracted for further use in automated analyzer.

It would have been obvious for any person of ordinary skill in the art to slightly modify Mazza's method by including information on the time period during which the sample can be retained in the storage space for further analysis the way it is taught by Thorne for the reagents, either because the samples can degenerate with time the same way the reagents do and become unacceptable for further analysis, or because the samples should be stored only for the time period when they might be required for re-testing, as indicated by Mazza. Therefore, it would have been obvious for any person of ordinary skill in the art to discard the samples which were retained in the storage compartment for the period of time exceeding the expiration date (the time period) and to alert the user about such expiration of the time period.

11. **Claim 5** is rejected under 35 U.S.C. 103(a) as being unpatentable over Mazza in view of Thorne, as applied to claims 1-4, 6 and 9-10 above, and further in view of the well known prior art, e.g. Boosalis et al. (US 4,362,698, IDS).

Although Mazza in view of Thorne do not specifically indicate using a protective film (layer, lid, foil, etc.), which can be easily removed or pierced, their use for covering the samples to be analyzed are well known in the art, as disclosed by e.g. Boosalis.

While Boosalis discloses a more complex cover for fluid sample cups, which serves many purposes and contains several layers, including film, adhesive tape, etc., it would have been obvious for anyone of ordinary skill in the art to use any simple cover for sample in Mazza's method, including film, foil, plastic, etc., which is just one layer of Boosalis' cover and which may serve exclusively for protection of the samples and, on the other hand, be easily removed or pierced, because it is a conventional way of protecting samples of biological analytes from contamination during analysis.

Response to Arguments

12. Applicant's arguments filed 05/27/08 have been fully considered but they are not persuasive.

The examiner raises more issues on unclarity of the language of the claims under 112, second paragraph, as indicated above.

Regarding the time period for storage and the tests to be performed, the connection between these two entities did not become clearer when the Applicants referred to paragraph

[0043] of the specification. Why performing a standard metabolic panel including Na, K, CI, CO2, GLUC, BUN, CREA, and CA predetermines that the second aliquot is retained in the storage vessel for two weeks? Why not for 4 weeks? Or two days? Does the standard metabolic panel test take two weeks? The relation between the metabolic panel test time and the storage time is unclear.

Regarding rejection of the pending claims over the prior art, the examiner is not quite sure, as to what the Applicants' remark,

> "what Young discloses in this section is no more than storing an original specimen on board an analyzer for possible subsequent processing as well as the use of indicia on the original sample container to identify tests to be conducted on the sample", might mean.

Also, it is not clear, as to what the Applicants mean by indicating that "Young does not teach "extracting first and second aliquot portions", "performing tests on the first portion" and "storing the second aliquot in the storage compartment for a predetermined time". Young specifically teaches:

> "Upon withdrawal of a test sample a specimen upon which *other* tests are to be run *is placed in storage* and is then submitted to another timed sequence of steps including sample withdrawal, testing and presentation of test results. The storage step may be included in the time sequence of steps." (col. 4, lines 10-16)

Thus, what the Applicants call "aliquots" Young calls "specimen" with exactly the same steps of withdrawing specimen for performing different tests and storing the specimen for performing "other tests".

The examiner would like to thank the Applicants for their correct interpretation of obviousness rejection of claims 4, 6, and 10 over Young. However, she disagrees with their conclusion of allowability of the pending claims over Young.

The Applicants' arguments regarding Mazza's teaching are not clear. Mazza teaches storing an aliquot of the sample in the storage compartment and performing the tests with this aliquot after the tests of the first aliquot are completed, exactly in the same way as it is recited in the preambles of all independent pending claims, except for he does not disclose that the storage time is indicated in the bar code. This deficiency is cured by the teaching of Thorne. It is not quite clear, how the disclosure of two weeks as the storage time referred to by the Applicants is related to the recitation of the pending claims. The pending claims recite that the predetermined

time is defined by the identity of tests, which assumes that it is defined by the time period during which the tests are performed.

The Applicants' arguments regarding the predetermined storage time are quite confusing. It appears that the predetermined time can be any time, and it is totally unrelated to the tests being performed, which contradicts the subject matter of the pending claims. It also becomes unapparent, as to how the predetermined storage time is defined.

The examiner has already indicated that the subject matter of the pending claims is contradictory and confusing. The preamble of the pending claims requires that the tests for the second aliquot were performed after the tests on the first aliquot are completed; the storage time is defined by the tests to be performed with the first aliquot; at the same time the tests on the second aliquot should be performed *during* the predetermined storage time. It's unclear, as to how all these time periods are related to each other.

In addition to unclarity of the pending claims and the Applicants' remarks, the Applicants statement, that the biological samples do not degrade if kept at room temperature (20 ^{o}C) and humidity of up to 75% seems to be quite puzzling. The examiner respectfully requests the Applicants to provide any evidence for such stability of blood samples. According to the Google search (not a reference relied upon for the rejections): "[h]igh quality DNA, RNA and biomarkers in large amounts are easily obtained making it a favorite specimen of many researchers and clinicians, unfortunately blood is also a significant biohazard potentially exposing technicians to viral and bacterial pathogens. Maintaining the viability of nucleic acids in the sample long term requires storage at ultra-low temperatures to prevent degradation" (see http://www.genvault.com/html/solutions/biosamples/blood.html).

In conclusion, the Applicants' arguments are not convincing and the rejections of the pending claims are maintained.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (571) 272-1257. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yelena G. Gakh/
Primary Examiner, Art Unit 1797

7/25/2008